

SEP - 2 1999



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In Re: Patent Term Extension
Application for
U.S. Patent No. Re. 35,524

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. Re. 35,524,¹ which claims the human drug product ETOPOPHOS® (etoposide phosphate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,017 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,017 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 5, 1998 (63 Fed. Reg. 41859). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1029) + 690 \\ &= 1,205 \text{ days}\end{aligned}$$

Since the regulatory review period began on September 4, 1991, after the patent issue date (February 27, 1990), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,205 days, would extend the patent from August 4, 2007 (35 U.S.C. § 154) to November 21, 2010, which is beyond the 14-year limit (the approval date is May 17, 1996, thus the 14 year limit is May 17, 2010). The period of extension is thus limited to May 17, 2010, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the

¹U.S. Patent No. 4,904,768 was reissued as U.S. Patent No. 35,524 on June 3, 1997. Both the original patent and the reissue patent claim the approved product.

patent from its original expiration date, August 4, 2007, to and including May 17, 2010, or 1,017 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,904,768
Granted	:	February 27, 1990
Reissued as	:	U.S. Patent No. Re. 35,524
Original Expiration Date	:	August 4, 2007
Applicant	:	Mark G. Saulnier et al.
Owner of Record	:	Bristol-Myers Squibb Company
Title	:	Epipodophyllotoxin Glucoside 4'-Phosphate Derivatives
Classification	:	536/17.1
Product Trade Name	:	ETOPOPHOS® (etoposide phosphate)
Term Extended	:	1,017 days
Expiration Date of Extension : May 17, 2010		

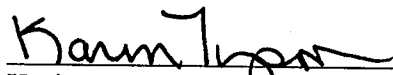
Any correspondence from applicant with respect to this matter should be addressed as follows:

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By FAX: (703) 308-6916
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Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
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RE: ETOPOPHOS®
FDA Docket No.: 96E-0270